

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Thomas Peter John GARRETT et al.  
Title: CRYSTAL STRUCTURE OF ERBB2 AND  
USES THEREOF  
Int'l. Appl. No.: PCT/AU2003/001310  
Int'l. Filing Date: October 6, 2003  
Examiner: Unassigned  
Art Unit: Unassigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

RELEVANCE OF EACH DOCUMENT

The documents being cited in the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding international application. A copy of the International Search Report is attached setting forth the portion of the documents considered relevant by the examiner. A copy of the cited references listed in the Search Report is not being submitted herewith.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 31 March 2005

By Stephen A. Bent

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Date Submitted: April 1, 2005

(use as many sheets as necessary)

Sheet 1 of 1

Application Number

JC13 Res 4 PCT/PTO 01 APR 2005

Filing Date

April 1, 2005

First Named Inventor

Thomas Peter John GARRETT

Group Art Unit

Unassigned

Examiner Name

Unassigned

Attorney Docket Number

051654-0106

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
/H.S./	A1	5 968 511		AKITA et al.	10/19/1999	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office <sup>2</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
/H.S./	A2		WO 99/31140		6/24/1999		
/H.S./	A3		WO 01/15730		3/8/2001		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>3</sup>
/H.S./	A4	International Search Report of PCT/AU03/01310.	
	A5	F. XU et al., "Antibody-Induced Growth Inhibition is Mediated Through Immunohistochemically and Functionally Distinct Epitopes on the Extracellular Domain of the c-erbB2 (HER-2/neu) Gene Product p. 185. International Journal of Cancer, Vol. 53, 1993, pp. 401-408.	
	A6	R. M. NEVE et al., "Biological Effects of anti-ErbB2 Single Chain Antibodies Selected for Internalizing Function", Biochemical and Biophysical Research Communications, Vol. 280, 2001, pp. 274-279.	
	A7	F. CENTIS et al., p. 185 HER2/neu Epitope Mapping with Murine Monoclonal Antibodies", Hybridoma, Vol. 11, No. 3, 1992, pp. 267-276.	
	A8	E. ENAN et al., "Activation of c-Neu Tyrosine Kinase by o,p'-DDT and $\beta$ -HCH in Cell-Free and Intact Cell Preparations from MCF-7 Human Breast Cancer Cells", Journal of Biochemical and Molecular Toxicology, Vol. 12, No. 2, 1998, pp. 83-92.	
	A9	X. LI et al., "Single-chain Antibody-mediated Gene Delivery into ErbB2-positive Human Breast Cancer Cells", Cancer Gene Therapy, Vol. 8, No. 8, 2001, pp. 555-565.	
	A10	I. STANCOVSKI et al., "Mechanistic Aspects of the Opposing Effects of Monoclonal Antibodies to the ERBB2 Receptor on Tumor Growth", Proceedings of the National Academy of Science, USA, Vol. 88, 1991, pp. 8691-8695.	
	A11	T. P. J. GARRETT et al., "The Crystal Structure of a Truncated ErbB2 Ectodomain Reveals and Active Conformation Poised to Interact with Other ErbB Receptors", Molecular Cell, Vol. 11, 2003, pp. 495-505.	
	A12	Y. L. YIP et al., "Structural Analysis of the ErbB-2 Receptor Using Monoclonal Antibodies: Implications for Receptor Signalling." International Journal of Cancer, Vol. 104, 2003, pp. 303-309.	
/H.S./	A13	J. SINGH et al., "Structure-Based Design of a Potent, Selective, and Irreversible Inhibitor of the catalytic Domain of the erbB Receptor Subfamily of Protein Tyrosine Kinases", Journal of Medicinal Chemistry, Vol. 40, 1997, pp. 1130-1135.	

Examiner Signature	/Hong Sang/	Date Considered	06/13/2008
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

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